K092530

1082

510(k) Summary **807.92(c)**

Sponsor APR - 2 2010 **807.92(a)(1)**

Submitter
Russell Walther
6026 Martel Avenue
Dallas, Texas 75206

Contact Person: Russell Walther
Telephone: 817-992-0232
Fax: 817-249-0771

Date Prepared: August 10, 2009

Device Name **807.92(a)(2)**

Proprietary Name:	Sprytie™ (models ST001, ST002, ST003)
Common/Usual Name:	Stainless Steel Wire for Maxillary and Mandibular Fixation
Classification:	Class II Dental Classification Panel Wire, Fixation, Intraosseous
Regulation Number:	872.4880
Product Code:	DZK

Predicate Devices **807.92(a)(3)**

Predicate Device #1:	Aragon Wiring System, K022821
Predicate Device #2:	Erich Arch Bar, K061271

Device Description **807.92(a)(4)**

The Sprytie™ is a 25, 26, or 27 gauge annealed 316L stainless steel wire 7 inches in length, with a hollow 22TW, 23TW, or 24TW sleeve crimped over one end of the wire, respectively.

K092530

The Sprytie™ is used in place of traditional light gauge stainless steel surgical wire during the placement of arch bars and splints, direct intraosseous wiring, bridal wire placement, and direct maxillomandibular fixation (ivy loops, risden wires, etc.). The sleeve end is inserted around the teeth first. The stiffness of the sleeve prevents the flexure of the wire.

Device Intended Use **807.92(a)(5)**

Sprytie™ wires are indicated for use in the jaws in adults and children to directly wire bony segments together, for the fixation of arch bars or splints to the teeth, for stabilization of bony segments, or for wiring the teeth together (maxillomandibular fixation).

Device Technological Characteristics **807.92(a)(6)**

The wire component of the Sprytie™ is identical to predicate devices. The Sprytie™ includes a ¾ inch 304 stainless steel sleeve crimped over one end. In predicate devices the wire is packaged in 75-675 ft length reusable spools. The predicate devices do not contain the 304 stainless steel portion.

Conclusion **807.92(b)(3)**

The Sprytie™ has the same intended use as predicate devices, as well as substantially equivalent technical specifications. The modification to a traditional 316L stainless steel wire with the addition of a 304 stainless steel sleeve improves the ease of use of the wire, and does not change the intended use of the wire. The Sprytie™ is as safe, as effective, and performs as well as or better than predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR - 2 2010

Mr. Russell B. Walther
Russell B. Walther
6026 Martel Avenue
Dallas, Texas 75206

Re: K092530
Trade/Device Name: Sprytie™
Regulation Number: 21CFR 872.4880
Regulation Name: Intraosseous Fixation Screw or Wire
Regulatory Class: II
Product Code: DZK
Dated: March 18, 2010
Received: March 24, 2010

Dear Mr. Walther:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092530

4-1
1071

Indications for Use

510(k) Number (if known):

Device Name: Sprytie™

Indications for Use:

Sprytie™ wires are indicated for use in the jaws in adults and children to directly wire bony segments together, for the fixation of arch bars or splints to the teeth, for stabilization of bony segments, or for wiring the teeth together (maxillomandibular fixation).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092530